

# Common Errors in SPL R4 Submissions

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- Missing folder
- Zipping the SPL file
- Inclusion of Thumbs.db file
- Including too many folders
- Submitting more than one XML file per folder
- Incorrect file name
- Not using the suffix element

# Missing Submission Folder

- **Issue:** SPL files are received without folder
- **Resolution:** SPL files including all image files are placed in a folder and sent through the FDA Gateway.

# Zipped Submissions

- **Issue:** Folder containing file is zipped and sent via Gateway
- **Resolution:** Do not zip folders containing SPL documents
- (Zipping the files is required to test the listing & image files via the Validator Lite tool but unzip prior to sending to FDA.)

# Too Many Folders

- **Issue:** Submission is nested in too many folders
- **Resolution:** Upload only one folder containing the files

# Incorrect Gateway Routing

- **Issue:** Sending Drug Establishment Registration and Listing submission to wrong Gateway “center”
- **Resolution:** The name of the “center” and the “type of submission” are used to properly route the files. For electronic drug registration and listing, the center is “OC” and the type of submission is “SPL”.

# Inclusion of Thumbs.db File

- **Issue:** Network “Thumbs.db” file is included with XML & JPEG files
- **Resolution:** See next slide

# Thumbs.db cont...

If you're on the desktop...

1. Click Start
2. Double-click Control Panel
3. Double-click Folder Options

Or, if you have My Computer open and are browsing any folder in your system...

1. Click Tools (next to File, Edit, View at the top of the screen)
2. Click Folder Options

After performing either of those two operations, the "Folder Options" window will open up.

1. Click on the View tab
  2. Check off the circle next to Do not cache thumbnails
  3. Click the Ok button
- Once you click the Ok button, your computer will cease to generate Thumbs.db files. If you delete any of the existing Thumbs.db files, they will not return. Be forewarned though, if you browse a folder that contains a large quantity of image files (or extremely large image files), it will take a long time for that folder to load even if you have previously browsed it because the thumbnail images will not have been cached in Thumbs.db."



# Multiple XML Files in One Submission

- **Issue:** More than one XML file is included in each drug listing or drug establishment registration submission
- **Resolution:** Ensure that only one XML file is included in each folder. Upload one folder at a time via Gateway.

# Suffix Element

- **Issue:** Including additional qualifiers (e.g. “tablets,” “Extended Release,” “XR”) in the proprietary name field
- **Resolution:** Place is the additional qualifiers in the suffix tag.

# Error Messages

- Check your Gateway My Submissions Inbox for error messages
- 2<sup>nd</sup> acknowledgement for a submission is indicative of error message
- A few error messages for complex issues will be sent via e-mail.

# Recommendations

- Read SPL R4 Step-by-Step instructions document

<http://www.fda.gov/downloads/ForIndustry/DataStandards/StructuredProductLabeling/UCM162027.pdf>

- Request assistance via SPL e-mail account – [spl@fda.hhs.gov](mailto:spl@fda.hhs.gov)

Questions